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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,731	05/17/2006	Kazumichi Uotani	0171-1273PUS1	8869

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
05/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/579,731	UOTANI ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/26/10*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is noted at the outset that the Examiner is open to Interview at any time, should such be deemed helpful in advancing prosecution/addressing the issues of record.

Applicant's response is noted, there were no claim amendments. Due to a new primary reference of record, the present action is sent Non-Final.

As noted previously, the present application has been transferred to the present Examiner by former Examiner Young. Applicant's response is acknowledged. The rejection as to the amended Product claims is made Final, and the action sent in the event Applicant wishes to consider any other amendments thereto, prior to Allowance of the Method claims. Applicant is welcome to telephone the Examiner to schedule an interview to advance prosecution as needed.

As well as that:

Previous Indication of Allowable Subject Matter-Still Vacated

Amended claims 20-28, drawn to methods of treat xerostomia/dry mouth were not found to be reasonably taught or suggested by the prior art of record, using a sialogogue comprising a polyglutamic acid, following consideration of Applicant's arguments and amendments and a review of the art of record. Pending the cancellation or amendment of the rejected product claims, if amended over the art of record, **an updated search of the art will follow as to the Method claims (and potential Product claims) and if still deemed free of the art, allowance thereof will be rendered.**

Unfortunately, at this time, the Examiner cannot extend the Allowance on the Method of Use claims 20-28, due to new art of record being uncovered on the updated search of the

art (a standard review before allowance). Thus, the art must be made of record and addressed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. I & II (US 2003/0017209 and US 20040013723; nearly same disclosure in each in para's 59 and 69 respectively) in view of Tanimoto et al. (US 5,447,732) and/or Yalpani (US 20040063612) (last two discussed in previous action, cited simply to show that various range amounts of PGA are well known to the ordinary skilled artisan), and Napolitano et al. (US 5496558 A; cited simply to show that sialogogues are well known to the ordinary skilled artisan to be put into various products (e.g. chewing gum) to effect their saliva producing ends).

The claimed invention is drawn to a method of treating xerostomia/dry mouth, using a sialogogue comprising a polyglutamic acid.

The art issue outstanding was whether there was motivation/suggestion in the art that it would have been predictable to use a sialogogue comprising polyGlu, in the treatment of xerostomia/dry mouth? The newly recited art raises this issue based on its teaching/suggestion with some of the previous art of record.

1. Parikh et al. I & II both teach teach monosodium glutamate (MSG) (as part of a small recognized group of agents), the sodium salt form of glutamic acid, is a known sialogogue that stimulates secretion of saliva - agents which are well known to be used for treating dry mouth/xerostomia/Sjogren's syndrome:

> [0059] The microcapsules of the present invention may also contain sialogogues or agents that stimulate the secretion of saliva. Such agents include, but are not limited to, ascorbic acid, fumaric acid, citric acid, tartaric acid, malic acid, gluconic acid, pilocarpine, mayweed (akkal-kadha), echinacea, coleus, gentian, prickly ash, licorice, ginger, yerba santa, cardomom, monosodium glutamate and mixtures thereof.

2. Tanimoto et al teach a composition containing poly-glutamic acid and its degradation products that will act as a mineral-absorption enhancer when used in foods, in a variety of forms, including beverages, gels, solids or powders. Tanimoto et al. also teach that poly-glutamic acid is naturally available in a non-isolated product of the bacterium *Bacillus natto,* and that the advantage of Tanimoto et al. invention is that poly-glutamic acid can be provided as a source of nutrition, in pure form, with less cost and labor (column 3, lines 52-68). Tanimoto et al also teach that poly-glutamic acid and its sodium or other salts can be used interchangeably (column 4, lines 60-62) and

that it can be readily used as or in food (column 4, lines 63-69, carried over to column 5, lines 1-52). In this regard Tanimoto et al further provide a recipe for beef curry in which sodium poly-glutamate is used as an ingredient (column 10, Example 10, lines 34-56, carried over to lines 1-15 of column 11. More food recipes incorporating sodium poly-glutamate are provided throughout the remainder of columns 11, 12, and 13. **Tanimoto et al claim compositions comprising 0.1-10% w/w poly-glutamate in claim 1 and similarly, with a concentration of 0.01-5% w/w in their claim 2, this broad range anticipating the instant claim 5 by overlap.** It can be appreciated that the incorporation of poly-glutamate into food items it can be consumed from one to as many times per day as desired or required, thus anticipating the instant claim 6. Tanimoto et al's claims 5-13 claim use of their composition comprising poly-glutamate in a range of food types (liquid, Solid or powder) and foodstuffs. The methods of providing the poly-glutamate composition to mammals are claimed in claims 14 and 15.

3. Yalpani et al. teach PGA or polyglutamic alone:

[0054] These in homogeneities and structural variabilities of chemically derived poly(amino acids) are reflected in the study of Hefti et al. cited above. The authors attempted to examine a number of poly(amino acids) derived by thermal polycondensation of amino acid precursors and their ability to stimulate growth of dissociated fetal rat forebrain neurons (Hefti, F., et al., Brain Res., 541, 273-83, 1991). **The authors studied either commercial homopolymers, e.g., .alpha.-polyglutamic acid with average molecular weights of up to 43,000 Da (from Sigma Chemical Co.) or copolymers (with Mw of 1,000-10,000 Da) containing multiple amino acid repeat units, e.g., aspartic acid, glutamic acid and tryptophan**. The authors were unable to correlate the observed activities to polymer structures. They acknowledged substantial compositional heterogeneities of the polymers, such as the presence pigments and significant amounts of non-peptide linkages. They noted significant inconsistencies in the performance of these materials as a given poly(amino acid) could display variable potencies and be active or inactive, depending on the conditions of its preparations. Similarly, a poly(tryptophan) was

inactive, whereas a copolymer of tryptophan and aspartic acid exhibited potency. The authors postulated that the presence of dicarboxylic acids was a prerequisite for activity. Hefti et al. also acknowledged close similarities in the activity of serum alone to those of their polymers.

Yalpani also teach in para 61, that such products may be administered orally.

4. Napolitano et al. teach that sialogogues are well known to the ordinary skilled artisan to be put into various products (e.g. chewing gum) to effect their saliva producing ends).

Brief Summary Text - BSTX (13):
In accordance with the present invention, a solid dosage form product for the relief of xerostomia is provided. The solid dosage form can be a lozenge, tablet, chewing gum, pastille or the like and contains three principle ingredients which are a lubricating polymer comprising polyethylene oxide, a sialogogue and a pharmaceutically acceptable, substantially non-cariogenic carrier. The composition preferably also contains a source of mineral ions and a source of fluoride.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use **a sialogogue comprising a polyglutamic acid to treat xerostomia/dry mouth, because:**

Parikh et al. I & II advantageously each teach monosodium glutamate (MSG), the sodium salt form of glutamic acid, is a known sialogogue that stimulates secretion of saliva - agents which are well known to be used for treating dry mouth/xerostomia/Sjogren's syndrome. Polyglutamic acid of the salt form of MSG is simply > 1 molecule of the same. Thus, if a single molecule works as a sialogogue, the skilled artisan would know that more than one molecule would also (e.g. any form of polyglutamic acid).

As for amounts thereof, an art-accepted routinely optimizable parameter absent evidence to the contrary, it is known that PGA used in range amounts of 10,000+ (Daltons) is also known, as Yalpani teaches, and in the 0.1 to 10% by weight of composition amount, as Tanimoto et al. teaches. Thus, all the elements of the claimed invention are known (the addition of such known additives as saccharin, etc. merely be known oral-based additions routinely selected and provided no unobvious advancement, e.g. Applicant's claims 2-3). So, the issue is why does the combination of the above render either a closed-ended (e.g. Applicant's claim 1) or open-ended (Applicant's claim 2) PGA composition obvious, that may be used for any oral product (under a products broadest reasonable interpretation, e.g. Applicant's claims 1-3 and 7-10) or in a method of treating xerostomia? Because of Applicant's current choice of transition phrases: the method claims leave e.g. Applicant's product claims 2-3 and 7-10, as well as method claims 4-6 open to PGA WITH ANYTHING ELSE for treating xerostomia (e.g. Johnson ref.). Similarly, Yalpani teach that PGA is known to be used alone in certain products (those tested in Yalpani (e.g. para 54) and administered orally (para 61); thus nothing would prevent the Yalpani product from being used alone, in an oral product, especially since an amino acid which are well known to be ingested orally (irrespective of what call (sialogogue, oral composition, food product, toothpaste, gum)).

Lastly, Napolitano et al. advantageously teach that sialogogues are well known to the ordinary skilled artisan to be put into various products (e.g. chewing gum) to effect their saliva producing ends.

For the reasons set forth above, relying first on the new primary reference Parikh et al. advantageously teaching that the sodium salt form of glutamic acid (MSG) is a known sialogogue/saliva stimulating agent – and thus by extension any poly-version thereof - in view of the teachings on amounts of polyGlu (e.g. amounts) with the combination of other references, it would have been predictable to successfully use polyGlu as a sialogogue/saliva stimulating agent to treat dry mouth/xerostomia.

Absent evidence to the contrary of some unexpected result using polyglutamic acid v. the sodium salt form thereof in MSG (OR that one or more of the amounts claimed provided improved function over a nonclaimed amount), the claimed invention is deemed obvious.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAA, 5/7/10

/Maury Audet/
Examiner, Art Unit 1654